

REMARKS

In the Office Action dated July 5, 2006, typographical errors were noted in claims 34 and 43, which had been corrected.

Claims 23-43 were rejected under 35 U.S.C. §112, second paragraph as being indefinite because the Examiner stated it is unclear whether the first/second pacing electrode and the first/second sensing electrode are separate elements or the same element. The Examiner noted the specification indicates that the electrodes may be the same electrode, and the Examiner has interpreted them to be either the same or separate.

This rejection is respectfully traversed, to the extent that the Examiner believes that any claim amendment was necessary to bring claims 23-43 into compliance with Section 112, second paragraph. Applicants submit that claims 23-43 are not "unclear" as to whether the aforementioned electrodes are the same electrodes or separate electrodes, but rather are generic, so as to encompass both possibilities. Simply because a claim is written in generic form does not render the claim indefinite. The Examiner has easily been able to interpret the intended scope and meaning of claims 23-43 for examination purposes, and the same would be true for a person of ordinary skill in the field of designing cardiac stimulation systems. Applicants submit the Examiner has interpreted claims 23-43 (on this point) with the meaning and scope as were intended when those claims were written. Therefore, claims 23-43 are not indefinite, and are in full compliance with all provisions of Section 112, second paragraph.

Claims 23, 25, 26, 31, 32, 35, 40 and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as

being obvious over, Florio et al. Claims 33, 34, 42 and 43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Florio et al. Claims 24, 27-30 and 36-39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Florio et al in view of Yonce et al.

These rejections are respectfully traversed for the following reasons.

As explained in the introductory portion of the present specification, a problem in the field of bi-ventricular pacing is associated with the fact that such devices are often used to provide pacing therapy to patients suffering from congestive heart failure (CHF). In such bi-ventricular pacing systems, as in other pacing systems, it is desirable to monitor and detect loss of capture, meaning the absence (for whatever reason) of an evoked response following the emission of a stimulation pulse from the bi-ventricular pacer. Conventionally, such loss of capture detection is undertaken by sensing in one or both ventricles, which involves the acquisition of intra-cardiac electrogram (IEGM) signals, the morphology of which is then analyzed to determine whether capture has occurred. In the context of bi-ventricular pacing, however, the symptoms of CHF sometimes make it difficult to distinguish between a true loss of capture and the occurrence of fusion. Fusion occurs when an intrinsic depolarization of the heart takes place simultaneously or substantially simultaneously with a stimulation pulse from the heart-stimulating device.

The method disclosed and claimed in the present application is for reliably distinguishing between the occurrence of a true loss of capture and the occurrence of fusion. This is accomplished in the method of independent claim 23 by, in a control circuit of an implanted device, making two determinations as to the fulfillment or non-fulfillment of different cardiac characteristics and, dependent on the

occurrence of respective combinations of fulfillment and non-fulfillment of both of those cardiac conditions, selectively operating the bi-ventricular pacing circuit differently.

In the penultimate step of independent claim 23, the two conditions (a) and (b) are linked by the word “and” which means that, in order for a reference to anticipate or obviate the method of claim 23, the reference must either disclose or suggest that *both* conditions (a) and (b) be detected or monitored. In other words, the method of claim 21 is not practiced if only (a) is determined to be fulfilled or not fulfilled, and no information is obtained as to whether (b) is fulfilled or not fulfilled. Conversely, the method of claim 23 would not be practiced if only information regarding the fulfillment or non-fulfillment of condition (b) were detected, but no information was detected as to whether condition (a) is fulfilled or not fulfilled. It is only by analyzing the combination of fulfillment and non-fulfillment of (a) and the fulfillment and non-fulfillment (b) that the aforementioned ability to distinguish between a real loss of capture and fusion is achieved.

As noted above, independent claim 23 as originally filed already included the word “and” between the descriptions of condition (a) and condition (b), thereby already making clear that determination of *both* conditions must be made in order to practice the method. Independent claim 21 has been amended consistent with the above discussion to make clear that this detection of both conditions (a) and (b) is for the purpose of distinguishing between a real loss of capture and fusion. Independent claim 23 also has been amended to make clear that the first and second pacing circuits are differently operated dependent on respective combinations of fulfillment and non-fulfillment of (a) and fulfillment and non-fulfillment

of (b). Again, by virtue of the use of the word "and" it is clear that all four occurrences (i.e. fulfillment of (a), non-fulfillment of (a), fulfillment of (b) and non-fulfillment of (b)) must be determined, in order to create the aforementioned combinations using the word "and."

Since similar considerations apply to conditions (c) and (d), claim 25 has been amended in the same manner.

Applicants submit that no such method is disclosed or suggested in the Florio et al reference.

The Florio et al reference makes no recognition of the potential problem of fusion with regard to detecting loss of capture in the context of bi-ventricular pacing, and therefore no efforts are disclosed in the Florio et al reference to identify or detect the possibility of fusion having occurred, much less the possibility of fusion having occurred and causing a false loss of capture detection or non-detection.

The Florio et al reference is exclusively concerned with detecting different types of capture situations, but does not recognize, nor address, the problem of capture being masked by fusion. As stated in paragraph [0022] of the Florio et al reference, the stimulation device and technique disclosed therein address the problem that as CHF progresses, dilation of the ventricles increases, causing the inter-ventricular conduction time to increase, and it is this problem, rather than fusion, that the morphology analysis disclosed in Florio et al reference is designed to address. This is summarized in paragraph [0025] of the Florio et al reference, which states that the device disclosed therein is capable of sensing, in a single sense channel, characteristics that permit the detection of non-capture, single-chamber capture, and bi-chamber capture. As stated in the next three paragraphs [0026],

[0027] and [0028], this is accomplished by a morphology analysis of either a complete IEGM signal, or a sampled IEGM signal.

In substantiating the rejection of claim 23 based on the Florio et al reference, the Examiner cited paragraph [0112] and paragraph [0114] of the Florio et al reference as corresponding to determining the aforementioned conditions (a) and (b) in claim 23. Applicants respectfully submit that those passages in the Florio et al reference do not describe detecting *both* conditions (a) and (b), nor do they disclose or suggest operating the pacemaker differently dependent on different combinations of fulfillment and non-fulfillment (a) and fulfillment and non-fulfillment of (b).

Paragraph [0112] of the Florio reference simply refers to detecting the number of negative peaks 162 within a sampling window 190 following emission of a stimulation pulse. As stated in paragraph [0113], once bi-ventricular capture is verified in the aforementioned step 315, the IEGM waveform representing bi-ventricular capture is stored as a template in a memory.

The procedure described in paragraph [0114] follows the aforementioned storage of the template. The ventricular stimulation pulse amplitude is decreased by a predetermined value and *another* IEGM waveform is sampled and stored. This new IEGM waveform is examined in a similar manner as in step 315, but this time the algorithm tests for criteria indicating single-chamber capture, namely by two distinct polarizations occurring after the stimulation pulse. As noted by the Examiner, these two polarizations may be detected as two negative peaks following the stimulation pulse within the sampling window. This is but one example of several examples that are then listed, another example being a second event detection at some time interval after a first event detection. In other words, the listing of the

possibilities in paragraph [0114] in the sentence beginning "For example,..." is not intended to list detection techniques that are used simultaneously or successively, but instead is a listing of *alternative* detection techniques that are implemented individually. This is clear because the Florio et al reference does not provide any teaching as to what would happen if more than one of these techniques were implemented in the same waveform, and different, conflicting results were obtained. There is no need in the Florio et al reference to disclose how to resolve such conflicts, because only one of those detection techniques is implemented, and therefore there will be no possibility for a conflict with some other detection technique to occur.

Moreover, as noted above, the procedure described in paragraph [0114] of the Florio et al reference *follows* the procedure described in paragraph [0112], and is implemented for a *different, subsequent* waveform from the waveform for which the procedure in paragraph [0112] was implemented. This is in contrast to the explicit language in claim 23, that requires the control circuit to be operated with time cycles corresponding to normal heart cycles, and condition (a) is stated to be determined during "a time cycle" and condition (b) is stated to be determined "during the same time cycle."

The Florio et al reference, therefore, does not disclose all of the elements of independent claim 23 as arranged and operating in that claim, and thus does not anticipate claim 23, nor any of claims 25, 26, 31, 32, 35, 40 or 41 depending therefrom.

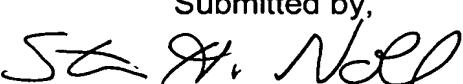
For similar reasons, claim 23 would not have been obvious to a person of ordinary skill in the field of designing bi-ventricular pacing systems based on the

teachings of the Florio et al reference, because, as noted above, the Florio et al reference does not even recognize, much less address, the problem of fusion and its relationship to detecting loss of capture. The Florio et al reference, therefore, is incapable of providing such a person of ordinary skill when any guidance or teaching to solve that problem, and specifically does not provide any guidance or teaching to solve that problem in the manner set forth in method claim 23. These arguments apply to claims 25, 26, 31, 32, 35, 40 and 41, depending from claim 23, that were rejected in the alternative as being obvious over the teachings of Florio et al, as well as claims 33, 34, 42 and 43 that were rejected solely as being unpatentable over Florio under 35 U.S.C. §103(a).

As to the rejection of claims 24, 27-30 and 36-39 based on the teachings of Florio et al and Yonce et al, those claims depend from claim 23 and therefore embody the subject matter of claim 23 therein. Therefore, even if the system disclosed in the Florio et al reference were modified in accordance with the teachings of Yonce et al, the subject matter of claims 24, 27-30 and 36-39 still would not result.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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